



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,305	06/27/2003	Liang C. Dong	ARC 3251 R1	8986
30766 7590 01/18/2007 DEWIPAT INCORPORATED P.O. BOX 1017 CYPRESS, TX 77410-1017			EXAMINER GOLLAMUDI, SHARMILA S	
			ART UNIT	PAPER NUMBER
			1616	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/18/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/608,305	Applicant(s) DONG ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,14-16 and 25-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-13 and 17-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1616

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group, claims 1-24; the species directed to a multilayer reservoir; HPMC; and polymethacrylate latex respectively in the reply filed on 8/4/06 and 11/16/06 is acknowledged. Accordingly claims 25-36 are withdrawn as being directed to a non-elected invention and claims 2-3, 14-16, are withdrawn as being directed to a non-elected species. Claims 1, 4-13, 17-23 are directed to the elected invention.

Claim Rejections - 35 USC § 102

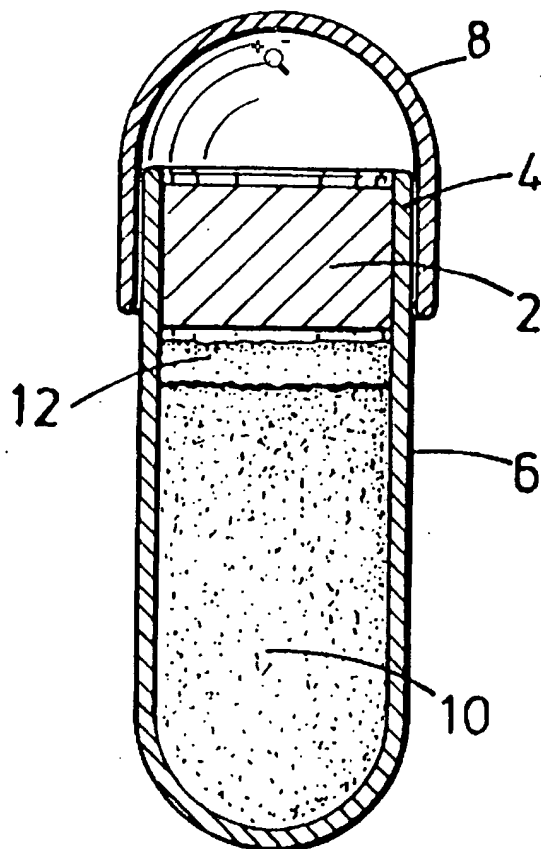
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by 5,897,874 (Steven et al).

Stevens et al disclose delivery device for delivering an active substance to a patient at a predetermined time.



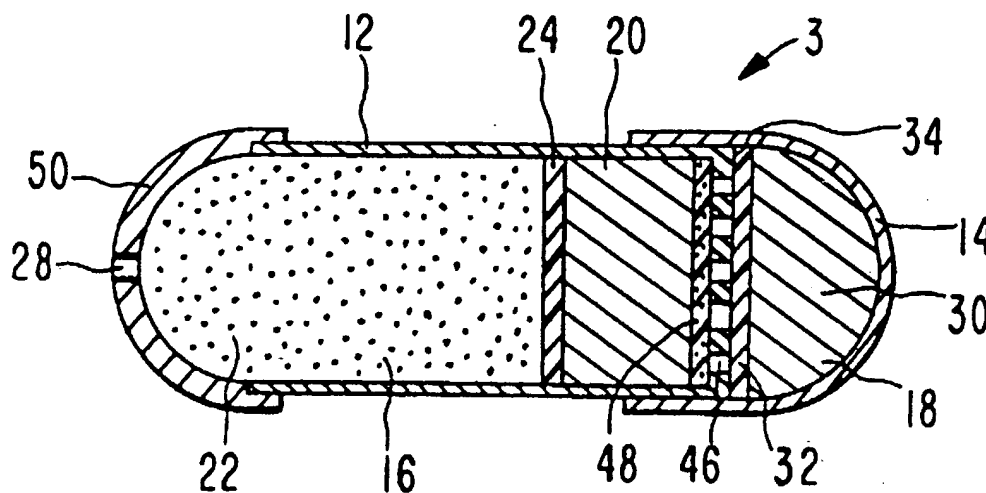
The body of the capsule, 6, is preferably a hard gelatin capsule that is coated with a water-impermeable coating including polyethylene, polypropylene, poly(methylmethacrylate), polyvinyl chloride, polystyrene, polyurethanes, polytetrafluoroethylene, nylons, polyformaldehydes, polyesters, cellulose acetate and nitro cellulose. See column 3, lines 5-25 and column 6, lines 18-21. Stevens discloses that the device can expel pharmaceutical as solid substances and liquids. The solid substance may be a capsule (e.g. a hard gelatin or soft gelatin capsule) containing a liquid to be delivered. See column 5, lines 20-25. The osmotic push layer, 10, is "at least partially" within the reservoir since the claim does not exclude the osmotic push

Art Unit: 1616

layer from being completely enclosed within the reservoir. See column 2, line 60 to column 3, line 5.

Claims 1, 4, 10-13, 17, 23-24 under 35 U.S.C. 102(b) as being anticipated by Wong (5,312,390).

FIG. 5



Wong discloses a osmotic device comprising a reservoir formed of wall (12) and (50) and housing a drug (16). Wong discloses wall (12) is made of an impermeable or an semipermeable membrane. See column 5, lines 55-60 and column 5, lines 55-60. Cap (5) is made of an impermeable or semipermeable material. See column 5, lines 45-46. Wong further discloses the delivery device is formulated by coating two portions of a hard gelatin capsule with an impermeable material and the other portion with semi-permeable material (this other portion is implicitly wall 14 since Wong discloses at least a portion of 14 has to be semipermeable). See column 10, lines 40-60. Note the gelatin layer reads on the "water permeable layer" of claim 4, i.e. forming the multilayer reservoir. The active is delivered as a liquid, solid, or semi-solid. See

Art Unit: 1616

column 6, lines 59-60. The reservoir further houses a osmotic expandable, push layer (20) and (30) wherein a semi-permeable membrane (46) covers a portion of the expandable, push layer (20). At least a portion of wall (14) must be semi-permeable. See column 5, lines 53-55. (28) is the exit orifice.

With regard to claim 11-13, the expandable, push layer is not completely encapsulated by wall (12) and (50) since portions of the surface are open by the screen (46). Thus, the semi-permeable membrane (46) forms over portion of the expandable, push layer that is not enclosed by the reservoir wall (12). Alternatively, both (20) and (30) which are expandable composition and are interpreted to make-up the instant expandable push layer and a portion, i.e. (30) is not enclosed by the reservoir (12) and (50) and a portion (20) is positioned in the opening of the reservoir.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-9 and 21-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Wong (5,312,390) in further view of Dong (WO 0035419).

The teachings of Wong have been set forth above. Wong teaches impermeable materials for which the first housing 12 may be prepared from include, for example, polyethylene, polystyrene, ethylene-vinyl acetate copolymers, Hytrel.RTM. polyester elastomers (Du Pont) and other impermeable materials known to the art. see column 10, lines 50-55.

Wong does not teach the instant impermeable polymethacrylate latex material.

Dong teaches a controlled release system comprising liquid drugs. See abstract. Dong while teaching a barrier layer that is impermeable to fluids, teaches suitable materials include latex materials such as latex of acrylate esters EUDRAGIT, polyester elastomers (Du Pont); Hytrel, etc. See page 19, lines 22-25 and page 20, lines 14-26.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wong and Dong and utilize the instantly claimed impermeable material for wall (12). One would have been motivated to do so with a reasonable expectation of similar results since Wong teaches the use of any impermeable material known in the art and Dong teaches latex of acrylate esters are known materials that are impermeable to fluids. Furthermore, Dong teaches the same impermeable materials taught by Wong and thus establishes the functional equivalency between the instant latex material and the prior art's.

Claims 5-7, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong (5,312,390) in further view of Digenis (5,672,359).

Art Unit: 1616

The teachings of Wong have been set forth above. As discussed above, Wong teaches when forming the device, two portions of a hard gelatin capsule may be coated, one with an impermeable material and the other with a semipermeable material.

Wong does not teach the instant hydrophilic polymer.

Digenis while teaches a hard capsule for controlled release, teaches the hard capsule made by made from hydrophilic materials such as gelatin or hydroxypropylmethyl cellulose. See column 1, lines 10-15.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wong and Dong and utilize HPMC as the material form the capsule portion. One would have been motivated to do so with a reasonable expectation of similar results since Digenis teaches hard capsules may be made from hydrophilic materials such as instant HPMC or gelatin. Thus, a skilled artisan would have been motivated to substitute the prior art's gelatin material with the instant hydrophilic material with a reasonable expectation of success since Digenis establishes the functional equivalency of the prior art's hydrophilic material and the instant hydrophilic material, i.e. both are hydrophilic materials that are used to form hard capsules.

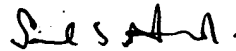
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

Art Unit: 1616

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sharmila S. Gollamudi
Examiner
Art Unit 1616